

DOCKET NO.: JJPR-0027 (ORT-1462)  
Application No.: 09/921,516  
Office Action Dated: November 26, 2003

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This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

1. (Original) A method comprising the steps in any order:
  - (a) administering an interferon dosing regimen to a subject in need thereof; and
  - (b) administering a therapeutically effective amount of erythropoietin (EPO) to the subject;wherein the erythropoietin improves the ability of the subject to maintain or increase the interferon dosing regimen.
2. (Original) The method of claim 1 wherein the interferon dosing regimen is administered as a single therapeutic agent.
3. (Original) The method of claim 1 wherein the interferon dosing regimen comprises administration of an interferon concurrently with a nucleoside analog.
4. (Original) The method of claim 3 wherein the nucleoside analog is selected from the group consisting of:
  - a) ribavirin (1- $\beta$ -D-ribofuranosyl 1H-1,2,4-Triazole-3-carboxamide);
  - b) AZT (3'-azido-3'-deoxythymidine);
  - c) 3TC (2R, cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one;
  - d) abacavir sulfate ((1 S, cis)-4-[2-amino-6-(cyclopropylamino)-9 H -purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1));
  - e) stavudine (d4T or 2',3'-didehydro-3'-deoxythymidine);
  - f) didanosine (dideoxyinosine or ddI);
  - g) zalcitabine (2',3'-dideoxycytidine or ddC)

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- h) Gemcitabine (2'-deoxy-2',2'-difluorocytidine monohydrochloride ((beta)-isomer); and
  - i) ganciclovir(9-[[2-hydroxy-1-hydroxymethyl]ethoxy]methyl] guanine).
5. (Original) The method of claim 4 wherein the nucleoside analog is ribavirin and where the interferon dosing regimen is administered to a subject with chronic hepatitis C.
6. (Original) The method of claim 4 wherein the nucleoside analog is ribavirin and where the interferon dosing regimen is administered to a subject for treatment of chronic hepatitis C (HCV) and the subject also in infected with human immunodeficiency virus (HIV).
7. (Original) The method of claim 1 wherein the interferon dosing regimen comprises an administration of an interferon concurrently with a protease inhibitor.
8. (Original) The method of claim 7 wherein the protease inhibitor is selected from the group consisting of:
- a) aquinavir (N-tert-butyl-decahydro-2- [2(R)-hydroxy-4-phenyl-3(S)-[[N-(2-quinolylcarbonyl)-L-asparaginy]amino]butyl]- (4aS,8aS)- isoquinoline-3(S)-carboxamide methanesulfonate);
  - b) itonavir (10-hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis (phenylmethyl)-, 5-thiazolylmethyl ester, (5S,8S,10S,11S)-2,4,7,12-Tetraazatridecan-13-oic acid); and
  - c) ndinavir (2,3,5-trideoxy-N-[(1S,2R)-2,3-dihydro-2-hydroxy-1H-inden-1-yl]-5-[(2S)-2-[[[(1,1-dimethylethyl) amino]carbonyl]-4-(3-pyridinylmethyl)-1-piperazinyl]-2-(phenylmethyl)-D-erythro-Pentonamide) and

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- d) wherein the interferon dosing regimen is used in a subject for the treatment of HIV.
9. (Original) The method of claim 1 wherein the interferon dosing regimen comprises administration of an interferon concurrently with an anti-tumor agent.
10. (Original) The method of claim 9 wherein the anti-tumor agent is selected from the group consisting of:
- a) cladribine (2-chloro-2'-deoxy-(beta)-D-adenosine);
  - b) Chlorambucil (4-[bis (2-chlorethyl) amino]benzenebutanoic acid);
  - c) DTIC-Dome (5-(3,3-dimethyl-1-triazeno)-imidazole-4-carboxamide);
  - d) cisplatin (cis-dichlorodiamineplatinum);
  - e) cyclophosphamide (2-oxide N,N-bis (2-chloroethyl) tetrahydro-2H-1,3,2-Oxazaphosphorin-2-amine);
  - f) fluorouracil (5-fluoro-2,4 (1H,3H)-Pyrimidinedione);
  - g) epirubicin (5,12-Naphthacenedione);
  - h) methotrexate (N-[4-[[[(2,4-diamino-6-pteridiny]methyl] methylamino] benzoyl]-L-Glutamic acid);
  - i) vincristine (22-oxo-Vincalukoblastine);
  - j) doxorubicin (10-[ (3-amino-2,3,6-trideoxy-a-L-lyxo-hexopyranosyl) oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy 5,12-Naphthacenedione);
  - k) bleomycin; and
  - l) etoposide ((5R,5aR,8aR,9S)-9-[[4,6-O-(1R)-ethylidene-b-D-glucopyranosyl] oxy]-5,8,8a,9-tetrahydro-5-(4-hydroxy-3,5-dimethoxyphenyl)-Furo [3',4':6,7] naphtho[2,3-d]-1,3-dioxol-6(5aH)-one).

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11. (Original) The method of claim 9 wherein the anti-tumor agent is fluorouracil and wherein the interferon dosing regimen is administered to a subject for treatment of colorectal cancer.
12. (Original) The method of claim 9 wherein the anti-tumor agent is cladribine and wherein the interferon dosing regimen is administered to a subject for treatment of Hairy Cell Leukemia.
13. (Original) The method of claim 9 wherein the anti-tumor agent is cladribine and wherein the interferon dosing regimen is administered to a subject for treatment of Multiple Sclerosis.
14. (Original) The method of claim 9 wherein the anti-tumor agent is Chlorambucil and wherein the interferon dosing regimen is administered to a subject for treatment of Lymphoma.
15. (Original) The method of claim 9 wherein the anti-tumor agent is Cisplatin and wherein the interferon dosing regimen is administered to a subject for treatment of solid tumors.
16. (Original) The method of claim 9 wherein the anti-tumor agent is cyclophosphamide and wherein the interferon dosing regimen is administered to a subject for treatment of Hematological malignancies.
17. (Original) The method of claim 9 wherein the anti-tumor agent is epirubicin and wherein the interferon dosing regimen is used in a subject for the treatment of bladder cancer.
18. (Original) The method of claim 9 wherein the anti-tumor agent is epirubicin and wherein the interferon dosing regimen is administered to a subject for treatment of renal cancer.

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19. (Original) The method of claim 9 wherein the anti-tumor agent is epirubicin and wherein the interferon dosing regimen is administered to a subject for treatment of ovarian cancer.
20. (Original) A method comprising the steps in any order:
  - a) administering an anti-viral regimen comprising an interferon and ribavirin to a subject in need thereof;
  - b) measuring hemolysis of said subject's red blood cells;
  - c) adjusting the amount of ribavirin provided to the subject such that a desired amount of hemolysis occurs; and
  - d) administering a therapeutically effective amount of erythropoietin (EPO) to the subject, wherein the erythropoietin improves an ability of the subject to maintain or increase the ribavirin dose.
21. (Original) The method of claim 20 wherein the desired amount of hemolysis is a reduction in the hemoglobin levels by about 20% within about one week of ribavirin administration.
22. (Original) The method of claim 20 wherein the amount of ribavirin administered is greater than 1200 mg/day for a subject weighing greater than 75 Kg or greater than 1000 mg/day for a subject weighing less than 75 Kg.
23. (Original) A method comprising the steps in any order;
  - a) administering an interferon dosing regimen to a subject with a chronic viral infection;
  - b) administering a therapeutically effective amount of erythropoietin (EPO) to the subject; and
  - c) administering a therapeutically effective amount of an anti-tumor necrosis factor compound to the subject; and

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- d) wherein the administration of the erythropoietin and the anti-tumor necrosis compound improves the ability of the subject to maintain or increase the interferon dosing regimen.
24. (Original) The method of claim 23, wherein the anti-tumor necrosis factor compound is selected from the group consisting of THALIDOMIDE, PENTOXIFYLLIN, INFLIXIMAB, glucocorticoids, and ETANERCEPT.
25. (Original) A method comprising the steps in any order;
- a) administering a interferon dosing regimen to a subject with chronic HCV;
  - b) administering a therapeutically effective amount of erythropoietin (EPO) to the subject; and
  - c) administering a therapeutically effective amount of an anti-tumor necrosis factor compound
  - d) wherein the administration of the erythropoietin and the anti-tumor necrosis compound improves the ability of the subject to maintain or increase the interferon dosing regimen.
26. (Original) The method of claim 25 wherein the interferon dosing regimen comprises administration of interferon concurrently with ribavirin.
27. (Original) The method of claim 26, wherein the anti-tumor necrosis factor compound is selected from the group consisting of THALIDOMIDE, PENTOXIFYLLIN, INFLIXIMAB, glucocorticoids, and ETANERCEPT.
28. (Original) The method of claim 25, wherein the anti-tumor necrosis factor compound is selected from the group consisting of THALIDOMIDE, PENTOXIFYLLIN, INFLIXIMAB, glucocorticoids, and ETANERCEPT.